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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,377	09/27/2006	Ulf Larsson	133087.12501(101420-1PUS)	7759

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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
08/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,377	LARSSON ET AL.	
	Examiner	Art Unit	
	/Venkataraman Balasubramanian/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 7-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5 and 7-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, which included amendment to claim1 and cancellation of claim 6, filed on 6/3/2009 has been entered. Claims 1, 3-5 and 7-20 are now pending. In view of applicants' response, the 102 rejection over Fisons has been obviated. In addition, since the claims of later filed copending application 11/591,464, no longer overlap with the instant process, the obviousness-type double patenting rejection made in the previous office action has been deemed as obviated. However, the following rejections are applied to currently pending claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7-12, 16, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Larsson et al., WO 01/92263.

Larsson et al., teaches a process for preparing compound of formula II from compound of formula III, which includes instant process of making compound of formula I from compound of formula III. See page 1 and 2 for process of making compound of formula Ii from compound of formula III and the process conditions. See example 3 shown in pages 12-14. Especially see page 14, step 4.

This rejection is same as made in the previous office action but now excludes cancelled claim 6. Applicants' traversal to overcome this rejection is not persuasive.

Contrary to applicants' urging, Larsson et al., teaches a process of making compound of formula I from compound of formula III by hydrogenation of azo group of compound of formula III to amino group of compound of formula I. This process is done with catalyst and hydrogen gas. Thus, the starting material (compound of formula III), the final product (compound of formula I), the reagent and the reaction conditions are all same as in instant process. Note in example 3, step for the reaction is done at 40º C. The overall process is done in one step. The fact that instant process recites the intermediate formed during the process is irrelevant as the overall process is for making compound of formula I. Applicants' argued that Larsson et al., did not teach the reaction at 20ºC. This is not entirely correct. In page 2, lines 12-15, Larsson teaches the conditions for the reaction including a temperature range of 10-70 ºC and for example 20-50 ºC. Hence, this rejection is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5 and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson et al., WO 01/92263 in view of Krauter et al., US 6,818,720.

Teachings of Larsson et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Larsson et al., teaches a process for preparing compound of formula II from compound of formula III, which includes instant process of making compound of formula I form compound of formula III. See page 1 and 2 for

process of making compound off formula Ii from compound of formula III and the process conditions. See example 3 shown in pages 12-14. Especially see page 14, step 4. Also note in page 2, lines 12-15, Larsson teaches the conditions for the reaction including a temperature range of 10-70 ºC and for example 20-50 ºC. Hence, this rejection is proper and is maintained.

Although Larsson et al. exemplifies one process with a specific starting material, catalyst and solvent, the process of reduction is nitro group to amino and azo to amino through hydrazo is known in the art.

The secondary reference Krauter et al., clearly teaches varying conditions for such hydrogenation process. See column 1-10 for details of the process and prior art.

One trained in the art would be motivated modify the catalyst, solvent and other experimental conditions.

Hence, one trained in the art would be motivated to make compound of formula I using the overall process taught by the combined references by varying the catalyst, solvent temperature and pressure of the reaction and expect to obtain the desired product because he would have expected the analogous starting materials and reactants react similarly in view of the combine teaching of the prior art. It has been held that application of an old process to an analogous material to obtain a result consistent with the teachings of the art would have been obvious to one having ordinary skill. Note In re Kerkhoven 205 USPQ 1069.

See also MPEP 2144.05, which says, under Optimization Within Prior Art Conditions or Through Routine Experimentation:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.). See also In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Also see In re KSR International vs. Teleflex Inc., 82 USPQ2d 13-85, 1397 (2007).

This rejection is same as made in the previous office action but now excludes cancelled claim 6. Applicants' traversal to overcome this rejection is not persuasive.

Contrary to applicants' urging, Larsson et al., teaches a process of making compound of formula I from compound of formula III by hydrogenation of azo group of compound of formula III to amino group of compound of formula I. This process is done with catalyst and hydrogen gas. Thus, the starting material (compound of formula III), the final product (compound of formula I), the reagent and the reaction conditions are all same as in instant process. Note in example 3, step for the reaction is done at 40º C. The overall process is done in one step. The fact that instant process recites the intermediate formed during the process is irrelevant as the overall process is for making compound of formula I.

Applicants' argued that Larsson et al., did not teach the reaction at 20ºC. This is not entirely correct. In page 2, lines 12-15, Larsson teaches the conditions for the reaction including a temperature range of 10-70 ºC and for example 20-50 ºC.

Also note In re KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007), the court stated that

[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Such is the case with instant claims. Larsson et al. exemplifies one process with a specific starting material, catalyst and solvent, the process of reduction is nitro group to amino and azo to amino through hydrazo is known in the art. The secondary

reference, Krauter et al., clearly teaches varying conditions for such hydrogenation process. See column 1-10 for details of the process and prior art. One trained in the art would be motivated modify the catalyst, solvent and other experimental conditions.

Hence, one trained in the art would be motivated to make compound of formula I using the overall process taught by the combined references by varying the catalyst, solvent temperature and pressure of the reaction and expect to obtain the desired product because he would have expected the analogous starting materials and reactants react similarly in view of the combine teaching of the prior art. Thus, the overall process is of ordinary skill and common sense.

Hence, this rejection is proper and is maintained.

Claims 1, 3-5 and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fisons EP 0508687, in view of Guile et al. WO 99/05143

Fisons teaches a process for preparing instant compound of formula I from instant compound of formula II, which includes instant process of making. See example 9, especially step iv.

Fisons differs from instant claims in not teaching use of transition metal catalyst for the reaction at 20ºC. However, reduction of nitro group by hydrogenation with transition metal is known in the prior art.

Guile teaches the nitro group can be reduced with by hydrogenation in presence of transition metal around room temperature or iron and acetic acid at 100ºC for structurally analogous compounds. See page 8, formula VII and note in lines 3-8, Guile teaches the conditions for hydrogenation including use of transition metal catalyst

around room temperature. See example 6, step a (page 21), example 12, step b (page 26), example 19, step d (page 33), example 24, step b(page 41) for use of iron and example 30 (page 46) and example 63(page 69) for use of transition metal catalyst.

Thus, Guile teaches equivalency of iron as reducing agent with hydrogenation with transition metal catalyst and provides examples to show viability of the reduction of the said nitro group.

One trained in the art would be motivated modify the catalyst, solvent and other experimental conditions for analogous compound of formula I.

Hence, one trained in the art would be motivated to make compound of formula I using the overall process taught by the combined references by varying the catalyst, solvent temperature and pressure of the reaction and expect to obtain the desired product because he would have expected the analogous starting materials and reactants react similarly in view of the combine teaching of the prior art. It has been held that application of an old process to an analogous material to obtain a result consistent with the teachings of the art would have been obvious to one having ordinary skill. Note In re Kerkhoven 205 USPQ 1069.

See also MPEP 2144.05, which says, under Optimization Within Prior Art Conditions or Through Routine Experimentation:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.). See also In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Also see In re KSR International vs. Teleflex Inc., 82 USPQ2d 13-85, 1397 (2007).

Also note In re KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007), the court stated that

[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Such is the case with instant claims. Fison exemplifies one process with a specific starting material, catalyst and solvent, the process of reduction is nitro group to amino is known in the art. The secondary reference, Guile clearly teaches use of iron as reducing agent and transition metal catalyst for such hydrogenation process. One trained in the art would be motivated modify the catalyst, solvent and other experimental conditions.

Hence, one trained in the art would be motivated to make compound of formula I using the overall process taught by the combined references by varying the catalyst, solvent temperature and pressure of the reaction and expect to obtain the desired product because he would have expected the analogous starting materials and reactants react similarly in view of the combine teaching of the prior art. Thus, the overall process is of ordinary skill and common sense.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5 and 7-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 3 of U.S. Patent No. 7,067,663. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process of hydrogenation of an azo intermediate embraced in the instant claims are also embraced in the compound and process of claims 3 and 2 of US 7,067,663. It would be obvious to one trained in the art to make the intermediate compound and hydrogenate it as embraced in the said US 7,067,663.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624